The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte AILEEN SONTAG TRANT

Appeal No. 2004-0974
Application No. 10/117,169

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-11 and 15. Claims 12-14 and 16 are also pending but have been withdrawn from consideration. Claims 1, 5, 10, and 11 are representative and read as follows:

1. A pharmaceutical composition having fertility promoting activity in males, comprising in combination components in effective amounts of antioxidants, including green tea, vitamin C, vitamin E or selenium, L-carnitine, ferulic acid in Dong quai, vitamins B6, B12, folate and zinc for oral ingestion for promoting fertility in males.

5. A pharmaceutical composition having fertility promoting activity in males comprising in combination components in effective amounts vitamins C

and E, selenium, ferulic acid, zinc and B vitamins for oral ingestion for promoting fertility in males.

10. A pharmaceutical composition of claim 5, further comprising components present in the proportion in parts by weight of

about 50% L-carnitine,
about 23% vitamins C and E,
about 8% Dong quai,
about 2% zinc and B vitamins, and
about 17% green tea.

11. A supplement for enhancing male fertility health, comprising antioxidants, green tea, vitamin C, vitamin E, and selenium for improving reproductive health, L-carnitine, vitamins B6 and B12 and zinc for promoting men's fertility for oral ingestion for promoting fertility in males.

The examiner relies on the following references:

Ashmead	4,774,089	Sept. 27, 1988
Liu	4,945,115	Jul. 31, 1990
Togasaki	5,788,971	Aug. 04, 1998
Craft	5,883,086	Mar. 16, 1999
Riley	5,976,568	Nov. 02, 1999
Newmark et al. (Newmark)	6,261,607	Jul. 17, 2001
Weil et al. (Weil)	DE 3931693 A	Apr. 04, 1991

Balch et al. (Balch), Prescription for Nutritional Healing, 2nd ed., pp. 338-339 (1997)

Scott et al. (Scott), "The Effect of Oral Selenium Supplementation on Human Sperm Motility," British Journal of Urology, Vol. 82, pp. 76-80 (1998)

Dawson et al. (Dawson), "Effect of Ascorbic Acid Supplementation on the Sperm Quality of Smokers," Fertility and Sterility, Vol. 58, no. 5, pp. 1034-1039 (1992)

Costa et al. (Costa), "L-Carnitine in Idiopathic Asthenozoospermia: a multicenter Study," Andrologia, Vol. 26, pp. 155-159 (1994)

Zheng et al. (Zheng), "Effects of Ferulic Acid on Fertile and Asthenozoospermic Infertile Human Sperm Motility, Viability, Lipid Peroxidation, and Cyclic Nucleotides," Free Radical Biology and Medicine, Vol. 22, no. 4, pp. 581-586 (1997)

Claim 5 stands rejected under 35 U.S.C. § 102(b) as anticipated by Craft.

Claim 11 stands rejected under 35 U.S.C. § 102(b) as anticipated by Riley.

Claims 1-11 and 15 stand rejected under 35 U.S.C. § 103 as obvious in view of Newmark, Balch, Dawson, Zheng, Liu, Scott, Costa, Weil, and Ashmead.

Claims 1-11 and 15 also stand rejected under 35 U.S.C. § 103 as obvious in view of Balch, Dawson, Zheng, Liu, Togasaki, Scott, Costa, Weil, and Ashmead.

We affirm the rejection of claim 5 for anticipation, and reverse the rejections for obviousness as applied to claims 5-9. We vacate the rejection of claim 11 for anticipation, as well as the obviousness rejections as applied to claims 1-4, 10, 11, and 15. We enter a new ground of rejection as to these claims.

Background

The specification discloses "combinations of beneficial bioeffecting compounds for promoting fertility in men. Sperm are highly susceptible to free radical or oxidative damage from environmental toxicants and natural aging. Vitamins C and E, green tea, and selenium are all potent antioxidants that help improve sperm counts and quality. Ferulic acid, an antioxidant found in Dong quai, also improves sperm quality. Zinc and B vitamins (B6, B12 and folate) are critical nutrients in male reproductive systems for hormone metabolism, sperm formation and motility. The amino acid, L-carnitine, promotes formation of healthy sperm. L-carnitine fumarate is preferred." Page 2.

Discussion

The claims are directed to compositions for promoting fertility in males, comprising some or all of the components described in the specification as having beneficial effects. The examiner rejected claims 5 and 11 as anticipated, and rejected all of the claims as obvious in view of either of two combinations of nine references.

We conclude that claims 1-4, 10, 11, and 15 are indefinite. Since we cannot determine their scope, we vacate the prior art rejections of these claims, and we will enter a new ground of rejection under 35 U.S.C. § 112, second paragraph. First, however, we will address the prior art rejections as applied to claims 5-9.

1. Anticipation

The examiner rejected claim 5 as anticipated by Craft. Claim 5 is directed to an orally ingestible composition "having fertility promoting activity in males," comprising "effective amounts" of vitamins C and E, selenium, ferulic acid, zinc, and "B vitamins". We interpret the latter limitation to require at least two B vitamins in the claimed composition.

The examiner pointed in particular to the embodiment described in Craft's claim 31. That claim describes a "nutritional supplement consisting essentially of," among other things, 5% to 2000% of the RDA of vitamins C and E; 5% to 500% of the RDA of selenium and zinc; 0.1-10 mg trans-ferulic acid; 0.5-25 mg vitamin B_6; and 2-50 mg vitamin B_{12}. See column 10, lines 10-21. This disclosure reasonably appears to meet all of the limitations of instant claim 5.

Appellant argues that Craft does not anticipate because "Craft relates to a cardiac care composition that requires DHEA [dehydroepiandrosterone] as a necessary component for alleviating irregular heart beat and for lowering blood pressure." Appeal Brief, page 6. Appellant points out that the male gender-specific formula disclosed by Craft also contains aspirin. Appellant argues that "Craft's teachings are contrary to the claimed invention. The invention does not require DHEA or aspirin." Id.

This argument is not persuasive. Instant claim 5 reads on compositions that include the recited components and anything else. See, e.g., Scanner Technologies Corp. v. ICOS Vision Systems Corp., 2004 WL 868404, at *6 (Fed. Cir. April 23, 2004) ("The use of the transitional phrase 'comprising' itself indicates that the elements or steps following the transition may be supplemented by additional elements or steps and still fall within the scope of the claim."). Thus, the composition disclosed by Craft falls within the scope of instant claim 5 and anticipates it.

Appellant also argues that "[t]he claimed composition is used for improving fertility, which is a feature neither described, contemplated nor desired by the Craft composition." Appeal Brief, page 6.

This argument is also unpersuasive. Instant claim 5 is directed to a composition, not a method of improving fertility. The fact that Appellant intends the claimed composition to be used to improve male fertility does not distinguish the claimed composition from the composition disclosed by Craft. Cf. Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("[W]here a

patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.").

2. Obviousness

The examiner rejected claims 5-9, among others, as obvious in view of either of two combinations of nine references. Claim 5 is the broadest of these claims. As previously noted, claim 5 is directed to an orally ingestible composition "having fertility promoting activity in males," comprising "effective amounts" of vitamins C and E, selenium, ferulic acid, zinc, and at least two B vitamins.

At the outset, we can set aside the following references that were cited by the examiner: Newmark, Togasaki, and Costa. These references relate to ingredients that are not required by claim 5 (green tea, green tea, and L-carnitine, respectively). Also, Liu was cited merely for its teaching that dong quai is a source of ferulic acid; since claim 5 is open to ferulic acid from any source, we need not further consider Liu.

We also will not consider the disclosure of Weil, because neither Appellant nor we have been provided a translation of the German-language reference. In both the first and final Office actions, the examiner relied on an English-language abstract of the reference, but in the Examiner's Answer, she cited to the full-text, German-language reference instead. The examiner noted that "a translation has been obtained and is included in the file," Examiner's Answer, page 16, but Appellant asserts that she has not been provided a copy of the translation. Reply

Brief, pages 1-2. We have been unable to locate a translation of Weil in the official Image File Wrapper. Since neither Appellant nor we have access to the translation that the examiner allegedly obtained, we will not consider Weil.

Thus, we are left with a rejection of claims 5-9 based on the combined disclosures of Balch, Dawson, Zheng, Scott, and Ashmead. Since these references were cited in both of the examiner's § 103 rejections, our analysis applies to both rejections.

The examiner characterized these references as follows: "Balch teaches using vitamin E, zinc, and vitamin B6 to treat impotence. . . . Dawson teaches using vitamin C to improve sperm quality. . . . Zheng teaches using ferulic acid to treat male infertility. . . . Scott teaches using selenium to improve sperm quality. . . . [Ashmead] teaches using vitamin B12 to improve male sexual health." Examiner's Answer, page 5. The examiner concluded that,

> [b]ased on the disclosure by the references that these substances are used in male fertility enhancing compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to improve male fertility. Therefore, the artisan would have been motivated to combine . . . vitamins C, E, B6, B12, selenium, . . . ferulic acid . . ., and zinc into a single composition.

Id., page 6.

Appellant argues that "[e]ach of the references has been relied on to pick and choose an element of the claimed invention using the present invention as a guide. However, such hindsight reconstruction cannot form an adequate basis for any obviousness holding." Appeal Brief, page 11.

"[T]he Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citation omitted). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000).

In this case, some of the references cited by the examiner can properly be combined and therefore suggest a composition comprising some of the components of instant claim 5. For example, Zheng discloses that ferulic acid "is beneficial to sperm viability and motility in both fertile and infertile individuals," (abstract); Scott discloses that "selenium supplementation in subfertile men with low selenium status can improve sperm motility and the chance of successful conception" (abstract); and Dawson discloses that "[a]scorbic acid supplementation of heavy smokers in excess of 200 mg/d results in improved sperm quality" (abstract).

Thus, each of these references suggests a specific active agent for producing the same physiological result. Therefore, these references can fairly be said to suggest combining ferulic acid, selenium, and vitamin C to produce a

composition for improving male fertility. However, we do not agree with the examiner that the references would have suggested adding to such a composition the additional components required by claim 5 – vitamin E, zinc, and at least two B vitamins.

The examiner relies on Balch and Ashmead as suggesting these components. The examiner notes that "Balch teaches using vitamin E, zinc, and vitamin B6 to treat impotence." Impotence, however, is not the same as male infertility. The problem addressed by Zheng, Scott, and Dawson is sperm viability and/or motility, while the problem addressed by Balch is inability to engage in sexual intercourse. See page 338. The examiner has not adequately explained why those skilled in the art would have expected that the nutritional supplements discussed by Balch would have any effect on sperm viability or motility; nor has the examiner explained why, in the absence of such an expectation, those skilled in the art would have been motivated to add those supplements to the composition suggested by Zheng, Scott, and Dawson.

The examiner characterizes Ashmead as "teach[ing] using vitamin B12 to improve male sexual health." We do not agree with this characterization of Ashmead's disclosure. Ashmead teaches that a composition comprising manganese, iron, and zinc, in the form of amino acid chelates, stimulates gonadotropin hormone production. Abstract. "In the male both libido and spermatogenesis are improved by the oral administration of the composition." Id. While Ashmead discloses that such compositions can also contain vitamins, it does not suggest that the vitamins themselves have any beneficial effect on

fertility. On the contrary, such additional components can be administered separately and are simply "beneficial to make sure that the animal is receiving a balanced vitamin and mineral preparation." Column 5, lines 20-27. Thus, we conclude that the examiner has not adequately shown that Ashmead would have suggested adding vitamin B12, specifically, to a composition for enhancing male fertility.

In sum, although we agree with the examiner that the cited references would have suggested combining some of the components recited in claim 5, we conclude that the claimed composition as a whole would not have been suggested by the cited references. We therefore reverse the rejection of claim 5. Claims 6-9 depend on claim 5 and therefore the rejection necessarily fails with respect to them as well.

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claims 1-4, 10, 11, and 15 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

Claims 1-4 and 15 are directed to a composition that includes, among other things, "antioxidants, including green tea, vitamin C, vitamin E or selenium." This limitation is indefinite. It is clear from the use of "antioxidants" that the composition must include at least two antioxidants. More than that, however, we cannot say. The claim language is open to at least three interpretations. It could mean that at least two antioxidants are required, and must be selected from those recited. Or it could mean that at least two antioxidants are required, and at

least one of them must be selected from those recited. Or it could mean that all of the recited antioxidants are required, despite the use of "or" in the claims.

The specification provides no assistance in distinguishing between the possible interpretations of the claim. The specification states that "preferred ranges" for the components of the compositions include 0-30% green tea and 0-3% selenium. See Example 2 on page 3. Thus, the specification implies that neither green tea nor selenium are essential components of the claimed composition. However, the specification does not provide any guidance on which antioxidants other than those listed in the claims could be used.

Similarly, claim 11 is directed to a composition that includes "antioxidants, green tea, vitamin C, vitamin E and selenium." This limitation is also open to multiple interpretations and therefore indefinite. It is unclear whether the claim requires only those antioxidants that are recited, or requires the recited antioxidants and at least two others in addition. The specification provides no assistance in distinguishing between the possible interpretations. The specification includes no exemplary compositions containing antioxidants other than those listed in the claims, and provides no guidance regarding other antioxidants that would be useful in the claimed composition.

Claim 10 is also indefinite, for a different reason. Claim 10 depends on claim 5, which is directed to a composition comprising vitamins C and E, selenium, ferulic acid, zinc, and at least two B vitamins. Claim 10 is directed to a composition having specific "proportion[s] in parts by weight" of L-carnitine (50%), vitamins C and E (23%, presumably combined), Dong quai (8%), zinc and

B vitamins (2%, presumably combined), and green tea (17%). The recited proportions, in parts by weight, add up to 100%. However, the recited components of the claimed composition do not include the selenium that is recited in claim 5.

A proper dependent claim must include all of the limitations of the claim from which it depends, 35 U.S.C. § 112, fourth paragraph, but claim 10 does not include all of the limitations of claim 5. Thus, it is unclear whether or not the composition of claim 10 includes selenium and, if so, what the correct proportions of both selenium and the other components of the claimed composition should be.

Since we cannot determine the metes and bounds of claims 1-4, 10, 11, and 15, we conclude that these claims are indefinite. Claims 1-4, 10, 11, and 15 are therefore rejected under 35 U.S.C. § 112, second paragraph.

Summary

We affirm the rejection of claim 5 as anticipated by Craft. We vacate the examiner's rejections of claims 1-4, 10, 11, and 15 and enter a new rejection of those claims as indefinite. However, we reverse the rejection of claims 5-9 as obvious in view of the references cited by the examiner. Thus, claims 6-9 are not subject to any outstanding rejection.

Time Period for Response

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)).

37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for

final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART, REVERSED-IN-PART,
VACATED-IN-PART, 37 CFR § 1.196(b)

Demetra J. Mills Administrative Patent Judge	)
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Eric Grimes Administrative Patent Judge	) APPEALS AND
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